

***United States Court of Appeals  
for the Second Circuit***



**APPENDIX**





ORIGINAL

**76-1353**

B  
PJS

**United States Court of Appeals**

**For the Second Circuit**

UNITED STATES OF AMERICA,

*Appellee,*

*against*

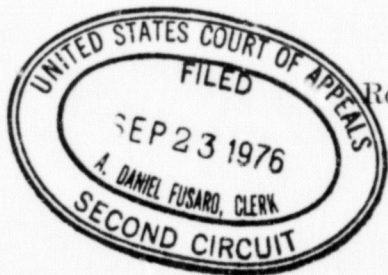
MARCEN LABORATORIES, Inc., a corporation, and  
RAPHAEL A. MAROTTA, an individual,

*Defendants-Appellants.*

ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK.

**APPENDIX.**

BROMSEN, GAMMERMAN, ALTIER & WAYNE  
*Attorneys for Defendants-Appellants*  
450 Seventh Avenue  
New York, N. Y. 10001



ROBERT B. FISKE, JR.  
*United States Attorney for the Southern  
District of New York*  
One St. Andrew's Plaza  
New York, N. Y. 10007

PAGINATION AS IN ORIGINAL COPY

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1a

UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT.

- - - - -X

UNITED STATES OF AMERICA,

*Appellee,*

*against*

MARCEN LABORATORIES, INC., a corporation, and  
RAPHAEL A. MAROTTA, an Individual,

*Defendants-Appellants.*

ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK.

- - - - -X

RELEVANT DOCKET ENTRIES.

| <u>DATE</u> | <u>PROCEEDINGS</u>                                                                                                                                                      |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1975        |                                                                                                                                                                         |
| 12-15       | Filed information.                                                                                                                                                      |
| 12-29       | Pleading adjourned to 1-5-76 on consent.<br>Frankel, J.                                                                                                                 |
| 1976        |                                                                                                                                                                         |
| 1-5         | Deft. (atty. present) Pleads not guilty.<br>Continued R.O.R. ordered photographed and<br>fingerprinted. Case assigned to Judge<br>MacMahon for all purposes. Bonsal, J. |

## RELEVANT DOCKET ENTRIES

| <u>DATE</u> | <u>PROCEEDINGS</u>                                                                                                                                                                                                                                                                                                                                                      |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1976        |                                                                                                                                                                                                                                                                                                                                                                         |
| 1-5         | Deft. (atty. for Corp. (Joseph P. Altier)<br>Pleads not guilty on behalf of the Corp. Case<br>assigned to Judge MacMahon for all purposes.<br>Bonsal, J.                                                                                                                                                                                                                |
| 1-6         | Filed Notice of Appearance for def't's. Joseph<br>P. Altier - Bromsen, Gammernan, Altier & Wayne,<br>450 7th Ave., NYC 10001 Lo 4-9090.                                                                                                                                                                                                                                 |
| 1-16        | Fld Govt's Memo of Law Re: the Elements of<br>proof for a viol of 21 USC 331 (d)                                                                                                                                                                                                                                                                                        |
| 1-16        | Fld Govt's Memo of Law Re: the elements of<br>Proof for a viol. of 21 USC 331(d)                                                                                                                                                                                                                                                                                        |
| 1-20        | Def't RAPHAEL MAROTTA present with Att'y<br>(Jos. Altier). Def't MARCEN LABS (by R.<br>Marotta, Pres.) Plead GUILTY to Counts<br>21, 22, 24 & 30. Raphael Marotta as an indiv-<br>idual plead GUILTY to Count 31. Mr. Marotta<br>signed waiver of rights for himself & Corp.<br>Sentence will be set after Judge decides con-<br>stitutional question.....MAC MAHON, J. |
| 1-22        | Filed Deft's acknowledgment of advice as to<br>constitutional rights.                                                                                                                                                                                                                                                                                                   |
| 1-30        | Filed Deft's memo in support of their motion<br>to dismiss the Information.                                                                                                                                                                                                                                                                                             |
| 2-6         | Fld Govt's Memo of Law in opposition to defts'<br>motion to dismiss the information                                                                                                                                                                                                                                                                                     |
| 3-11        | Filed transcript of record of proceedings,<br>dated 1-21-76                                                                                                                                                                                                                                                                                                             |
| 3-24        | Filed transcript of record of proceedings,<br>dated 1-16-76                                                                                                                                                                                                                                                                                                             |



## RELEVANT DOCKET ENTRIES

| <u>DATE</u>       | <u>PROCEEDINGS</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1976              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 6-11              | Filed Opinion #44560 & Order. Defts move to dismiss the information, claiming that the statute on which the charges are based is unconstitutional. Defts pled guilty on 1-20-76, but, before accepting their pleas, we approved a stipulation between counsel which provides that the pleas could be withdrawn if defts should prevail on their instant motion. The information charges that defts introduced into interstate commerce "new drugs" in violation of the federal Food, Drug & Cosmetic Act of 1938, as amended, 21 U.S.C. §§ 301 et seq. For the reasons indicated, the defts motion to dismiss the information is denied. So Ordered, MAC MAHON, J. n/m |
| 7-27<br>(#76,755) | Filed Judgment & Probation/Commitment Order<br>The Deft is FINED ONE THOUSAND (\$1,000.)<br>DOLLARS on each of COUNTS 21, 22, 24, and 30<br>for a total fine of FOUR THOUSAND (\$4,000.)<br>DOLLARS. Payment of the fines is stayed pending Appeal....MacMAHON, J. ( <u>Other COUNTS OPEN pending outcome of Appeal</u> )                                                                                                                                                                                                                                                                                                                                              |
| 7-30              | Filed Deft's Notice of Appeal to the U.S.C.A., for the 2nd Circuit from the Judgment of conviction entered 7-27-76. (m/n's)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 8-11              | Tried deft designation of exhibits on appeal                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

## INFORMATION.

## COUNTS ONE THROUGH THIRTY-FIVE.

The United States Attorney charges:

On or about the dates hereinafter set forth below in Counts One through Thirty-five, in the Southern District of New York, MARCEN LABORATORIES, INC., a corporation, and RAPHAEL A. MAROTTA, an individual, the defendants in violation of Title 21, United States Code, Section 331(d), unlawfully did cause to be introduced and delivered for introduction into interstate commerce at New Rochelle, New York, for delivery to the companies described below, certain drugs, which were new drugs within the meaning of Title 21, United States Code, Section 321(p), and were in violation of Title 21, United States Code, Section 355(a) in that no approvals of applications filed pursuant to Title 21, United States Code, Section 355(b), were effective with respect to such drugs:



5a

## INFORMATION

| <u>COUNT</u> | <u>DATE</u>                          | <u>COMPANY</u>                                              | <u>DRUG</u>                  |
|--------------|--------------------------------------|-------------------------------------------------------------|------------------------------|
| 1            | June 9, 1972                         | Advance Drug and<br>Surgical Supply,<br>San Antonio, Texas  | Ossionate Plus<br>Injectable |
| 2            | June 9, 1972<br>to<br>June 26, 1972  | Advance Drug and<br>Surgical Supply<br>San Antonio, Texas   | Lipo-k<br>Capsules           |
| 3            | June 9, 1972                         | Advance Drug and<br>Surgical Supply<br>San Antonio, Texas   | Lipo-k<br>Injectable         |
| 4            | June 9, 1972                         | Advance Drug and<br>Surgical Supply<br>San Antonio, Texas   | Normotensin<br>Injectable    |
| 5            | June 9, 1972                         | Advance Drug and<br>Surgical Supply<br>San Antonio, Texas   | Viro-Zyme<br>Injectable      |
| 6            | August 4, 1972                       | Quaker City<br>Pharmacal Co.,<br>Inc., Philadelphia,<br>Pa. | Viro-Zyme<br>Injectable      |
| 7            | June 9, 1972<br>to<br>August 4, 1972 | Quaker City<br>Pharmacal Co.,<br>Inc., Philadelphia,<br>Pa. | Lipo-K<br>Injectable         |
| 8            | August 4, 1972                       | Quaker City<br>Pharmacal Co.,<br>Inc., Philadelphia,<br>Pa. | Lipo-K                       |
| 9            | July 21, 1972<br>to                  | Quaker City<br>Pharmacal Co.,<br>Inc., Philadelphia,<br>Pa. | Ossionate Plus<br>Injectable |
| 10           | August 4, 1972                       | Quaker City<br>Pharmacal Co.,<br>Inc., Philadelphia,<br>Pa. | Normotensin<br>Injectable    |



## INFORMATION

| <u>COUNT</u> | <u>DATE</u>       | <u>COMPANY</u>                                           | <u>DRUG</u>                  |
|--------------|-------------------|----------------------------------------------------------|------------------------------|
| 11           | June 22, 1972     | Arden Pharmacal Co.,<br>Portland, Oregon                 | Ossionate 75<br>Injectable   |
| 12           | June 22, 1972     | Arden Pharmacal Co.,<br>Portland, Oregon                 | Ossionate<br>Plus Injectable |
| 13           | June 13, 1972     | Arden Pharmacal Co.,<br>Portland, Oregon                 | Ossionate<br>Capsules        |
| 14           | June 22, 1972     | Arden Pharmacal Co.,<br>Portland, Oregon                 | Ossionate<br>Plus Capsules   |
| 15           | June 22, 1972     | Arden Pharmacal Co.,<br>Portland, Oregon                 | Normotensin<br>Injectable    |
| 16           | November 15, 1971 | Arden Pharmacal Co.,<br>Portland, Oregon                 | Lipo-K<br>Injectable         |
| 17           | June 22, 1972     | Arden Pharmacal Co.,<br>Portland, Oregon                 | Lipo-K<br>Capsules           |
| 18           | June 22, 1972     | Arden Pharmacal Co.,<br>Portland, Oregon                 | Viro-Zyme<br>Injectable      |
| 19           | November 21, 1974 | Quaker City Pharmacal<br>Co., Inc.,<br>Philadelphia, Pa. | Ossionate 75<br>Injectable   |
| 20           | November 21, 1974 | Quaker City Pharmacal<br>Co., Inc.,<br>Philadelphia, Pa. | Lipo-K<br>Injectable         |
| 21           | January 27, 1975  | Quaker City Pharmacal<br>Co., Inc.,<br>Philadelphia, Pa. | Ossionate<br>Plus            |
| 22           | January 27, 1975  | Quaker City Pharmacal<br>Co., Inc.,<br>Philadelphia, Pa. | Normotensin<br>Injectable    |
| 23           | January 27, 1975  | Quaker City Pharmacal<br>Co., Inc.,<br>Philadelphia, Pa. | Lipo-K<br>Injectable         |
| 24           | January 28, 1975  | Quaker City Pharmacal<br>Co., Inc.,<br>Philadelphia, Pa. | Viro-Zyme<br>Injectable      |

## INFORMATION

| <u>COUNT</u> | <u>DATE</u>      | <u>COMPANY</u>                                        | <u>DRUG</u>             |
|--------------|------------------|-------------------------------------------------------|-------------------------|
| 25           | January 28, 1975 | Quaker City Pharmacal Co., Inc.,<br>Philadelphia, Pa. | Ossionate Plus          |
| 26           | January 28, 1975 | Quaker City Pharmacal Co., Inc.,<br>Philadelphia, Pa. | Lipo-K Capsules         |
| 27           | January 28, 1975 | Texas Vitamin Co.,<br>Dallas, Texas                   | Lipo-K Capsules         |
| 28           | January 28, 1975 | Texas Vitamin Co.,<br>Dallas, Texas                   | Ossionate Plus Capsules |
| 29           | February 4, 1975 | Texas Vitamin Co.,<br>Dallas, Texas                   | Lipo-K                  |
| 30           | March 5, 1975    | Texas Vitamin Co.,<br>Dallas, Texas                   | Lipo-K                  |
| 31           | March 5, 1975    | Texas Vitamin Co.,<br>Dallas, Texas                   | Lipo-K Capsules         |
| 32           | March 5, 1975    | Texas Vitamin Co.,<br>Dallas, Texas                   | Ossionate Plus Capsules |
| 33           | March 7, 1975    | Texas Vitamin Co.,<br>Dallas, Texas                   | Ossionate Plus Capsules |
| 34           | March 14, 1975   | Texas Vitamin Co.,<br>Dallas, Texas                   | Normotensin Injectable  |
| 35           | March 31, 1975   | Texas Vitamin Co.,<br>Dallas, Texas                   | Lipo-K Capsules         |

(Title 21, United States Code, Sections 321(p), 331(d)  
333(a), 355(a), and 355(b).)

THOMAS J. CAHILL  
United States Attorney for the  
Southern District of New York



## OPINION.

SOUTHERN DISTRICT OF NEW YORK.

## APPEARANCES:

BROMSEN, GAMMERMAN, ALTIER & WAYNE, Attorneys for Defendants, 450 Seventh Avenue, New York, N. Y. 10021.

ROBERT B. FISKE, JR., ESQ., U. S. Attorney, Southern District of N. Y., Attorney for United States of America, By: LAWRENCE B. PADOWITZ, ESQ., Asst. U. S. attorney; ARTHUR N. LEVINE and DONALD O. BEERS, ESQS., Attorneys, Food and Drug Administration, United States Courthouse Annex, One St. Andrew's Plaza, New York, N. Y. 10007.

*MacMAHON, District Judge.*

Defendants move to dismiss the information, claiming that the statute on which the charges are based is unconstitutional. Defendants pled guilty on January 20, 1976, but, before accepting their pleas, we approved a stipulation between counsel which provides that the pleas could be withdrawn if defendants should prevail on their instant motion.

The information charges that defendants introduced into interstate commerce "new drugs," in violation of the federal Food, Drug and Cosmetic Act of 1938, as amended, 21 U. S. C. §§ 301 *et seq.* ("The Act"). The

## OPINION

Act establishes a system of premarketing clearance for drugs. Certain drugs designated as "new drugs" by the Food and Drug Administration ("FDA") cannot be sold in interstate commerce unless a new drug application ("NDA") is approved by the FDA. The FDA is to determine the status of a drug pursuant to the definition set out in § 321(p) of the Act. That section provides that a "new drug" is any drug "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ." Defendants contend that this definition of "new drug" is unconstitutionally vague and therefore cannot support a criminal conviction.

It is a basic principle of due process that a criminal statute must give a person of ordinary intelligence a reasonable opportunity to know what is prohibited so that he can act accordingly. A statute will be void for vagueness if its prohibitions are not clearly defined.<sup>1</sup>

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1. *Grayned v. City of Rockford*, 408 U. S. 104, 108 (1972).



## OPINION

In non-First Amendment cases, however, a vagueness challenge must be examined in the context of the facts of each case.<sup>2</sup> Here, the fact that the general public is unable adequately to protect itself in the purchase of food and drugs imposes a high degree of responsibility on those who profit from their manufacture and sale and affects their obligations under regulatory legislation.<sup>3</sup> A regulatory statute in the food and drug industry is not invalid because there may be difficulty in determining whether certain marginal offenses fall within the prohibited area.<sup>4</sup> A person who has received fair warning of the criminality of his own conduct cannot attack a statute because the language would not give similar fair warning to other individuals that their conduct is also prohibited.<sup>5</sup>

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2. *United States v. Mazurie*, 419 U. S. 544, 553 (1975); *United States v. National Dairy Products Corp.*, 372 U. S. 29, 32-33 (1963).

3. *United States v. Wiesenfeld Warehouse Co.*, 376 U. S. 86, 91 (1964); *United States v. Dotterweich*, 320 U. S. 277, 280 (1943).

4. *United States v. National Dairy Products Corp.*, *supra*.

5. *Parker v. Levy*, 417 U. S. 733, 756 (1974).

## OPINION

The facts cannot support defendants' claim that they did not know that the drugs sold by them were "new" within the meaning of the Act. The FDA has complete authority to determine which drugs are "new" and require an approved NDA in order to be sold to the public. Defendants were aware, with respect to every count to which they pled guilty, that the drugs were considered to be "new drugs" without an approved NDA.

Defendant corporation admitted, with respect to each drug mentioned in Counts 21, 22, 24 and 30, that there had been at least one seizure by the FDA and that the FDA considered the drug to be a "new drug." Moreover, there had been at least one hearing under § 355 of the Act where defendant was able to contest the "new drug" designation. As to Count 31, to which defendant Marotta pled guilty as an individual, there was a § 355 hearing, publication in the Federal Register, and a letter to defendant Marotta stating that the FDA considered the drug to be a "new drug."<sup>7</sup> Since both defendants received actual notice that the FDA considered the subject drugs "new drugs" and knew that there was no effective NDA permitting their sale, defendants are in no position to claim that they were unable to guide their conduct so as to avoid criminal liability.

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7. Transcript of January 20, 1976, pp. 19-22.



12a

OPINION

Accordingly, defendants' motion to dismiss the  
information is denied.

So ordered.

DATED: New York, N. Y.  
June 11, 1976

LLOYD F. MacMAHON  
United States District Judge

13a

JUDGMENT APPEALED FROM.

UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK.

- - - - -X

UNITED STATES OF AMERICA,

vs.

RAPHAEL A. MAROTTA,

*Defendant.*

Information No. 75 Cr. 1200-LFM.

- - - - -X

JUDGMENT AND PROBATION/COMMITMENT ORDER.

COUNSEL:

In the presence of the attorney for the government the defendant appeared in person on this date: July 17, 1976, with counsel Ira Gammernan.

PLEA:

Guilty, and the court being satisfied that there is a factual basis for the plea.

FINDING & JUDGMENT:

Defendant has been convicted as charged of the offense of unlawfully causing to be introduced and delivered for introduction into interstate commerce



## JUDGMENT APPEALED FROM

a new drug, as specified in Count 31, without approval of the Department of Health, Education and Welfare, in violation of 21 U. S. C. Sections 321(p), 331(d), 333(a), 355(a) and 355(b).

## SENTENCE OR PROBATION ORDER:

The Court asked whether defendant had anything to say why judgment should not be pronounced. Because no sufficient cause to the contrary was shown, or appeared to the court, the court adjudged the defendant guilty as charged and convicted and ordered that: The defendant is hereby committed to the custody of the Attorney General or his authorized representative for imprisonment for a period of TEN (10) DAYS and is fined ONE THOUSAND (\$1,000) DOLLARS on Count 31. Execution of the prison sentence and payment of the fine are stayed pending appeal.

## ADDITIONAL CONDITIONS OF PROBATION:

In addition to the special conditions of probation imposed above, it is hereby ordered that the general conditions of probation set out on the reverse side of this judgment be imposed. The Court may change the conditions of probation, reduce or extend the period of probation, and at any time during the probation period

15a

JUDGMENT APPEALED FROM

or within a maximum probation period of five years permitted by law, may issue a warrant and revoke probation for a violation occurring during the probation period.

COMMITMENT RECOMMENDATION:

The court orders commitment to the custody of the Attorney General and recommends,

DATED: July 27, 1976

LLOYD F. MacMAHON  
U. S. D. J.

(Seal.)



JUDGMENT APPEALED FROM.

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK.

- - - - -X

UNITED STATES OF AMERICA,

*vs.*

MARCEN LABORATORIES, INC.,

*Defendant.*

Information No. 75 Cr. 1200-LFM.

- - - - -X

JUDGMENT AND PROBATION/COMMITMENT ORDER.

COUNSEL:

In the presence of the attorney for the government the defendant appeared in person on this date: July 27, 1976, with counsel, Ira Gammerman.

PLEA:

Guilty, and the court being satisfied that there is a factual basis for the plea.

FINDING & JUDGMENT:

Defendant has been convicted as charged of the offense of unlawfully causing to be introduced and delivered for introduction into interstate commerce

## JUDGMENT APPEALED FROM

certain new drugs, as specified in Counts 21, 22, 24 and 31, without approval of the Department of Health, Education and Welfare, in violation of 21 U.S.C. Sections 321(p), 331(d), 333(a), 355(a) and 355(b).

## SENTENCE OR PROBATION ORDER:

The court asked whether defendant had anything to say why judgment should not be pronounced. Because no sufficient cause to the contrary was shown, or appeared to the court, the court adjudged the defendant guilty as charged and convicted and ordered that: The defendant is fined ONE THOUSAND (\$1,000) DOLLARS on each of Counts 21, 22, 24 and 31 for a total fine of FOUR THOUSAND (\$4,000) DOLLARS. Payment of the fines is stayed pending appeal.

## ADDITIONAL CONDITIONS OF PROBATION:

In addition to the special conditions of probation imposed above, it is hereby ordered that the general conditions of probation set out on the reverse side of this judgment be imposed. The Court may change the conditions of probation, reduce or extend the period of probation, and at any time during the probation period or within a maximum probation period of five years permitted by law, may issue a warrant and revoke probation for a violation occurring during the probation period.



18a

JUDGMENT APPEALED FROM

COMMITMENT RECOMMENDATION:

The court orders commitment to the custody of the  
Attorney General and recommends,

DATED: July 27, 1976

LLOYD F. MacMAHON  
U. S. D. J.

(Seal.)

GOVERNMENT EXHIBIT--LETTER, DATED JUNE 15, 1972.

June 15, 1972

Marcen Laboratories, Inc.  
22 Lawton Street  
New Rochelle, New York 10801

Re: Lipo-K Capsules

Gentlemen:

This letter is in reference to the above product which you distribute containing choline salts and methionine.

On March 24, 1971 and March 25, 1971, announcements were published in the Federal Register, copies enclosed, setting forth the conclusion of the Food and Drug Administration that there is a lack of substantial evidence that choline, and/or methionine, will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling (as adjunctive therapy for those disorders of the liver, principally cirrhosis, where accumulation of fat is a factor; and assist the body in the metabolism of fat). Additionally, there is a lack of substantial evidence that choline and/or methionine deficiency is related to fatty liver and cirrhosis in humans. Lipotropic agents have not proved supplementally effective in clinical studies.

Accordingly, the Commissioner of Food and Drugs has withdrawn approval of the New Drug Applications for these drugs. Because your product is a related drug i.e. contains choline salts and methionine and is offered for similar purposes as the drugs named in the March 24 and 25 announcements, we regard it to be subject to the terms of the announcements and, therefore, a new drug for which an approved new drug application is not in effect and misbranded under the appropriate provisions of the Federal Food, Drug and Cosmetic Act. Please see the attached Federal Register statement of February 10, 1972, Applicability of DESI Notice to Identical, Related, and Similar Drug Products.

Thus, the continued marketing of this drug in interstate commerce is regarded to be in violation of the Act in that it is misbranded and a new drug without an approved new drug application. Outstanding stocks of the article in trade channels are subject to regulatory proceedings under the appropriate provisions of the Act.



## GOVERNMENT EXHIBIT

Page 2 - Marcen Laboratories, Inc.

We are taking this opportunity to bring to your attention the Federal Register announcement of August 25, 1970 concerning a combination drug containing Oxbile Extract, which is also a component of your product, setting forth the conclusion of the Food and Drug Administration that there is a lack of substantial evidence that the drug is effective for use as a cholagogue and choleretic in cases of insufficient bile flow, for use in treatment of cholecystitis, biliousness, intestinal indigestion and similar disorders associated with hepatic torpor, and for occasional constipation.

We request your reply within 15 days after receipt of this letter stating your intentions with respect to the continued marketing of this drug and removal of all outstanding stocks from trade channels down to the retail level. In addition, in the event you have already discontinued marketing, we would appreciate particulars on the following: 1) date discontinued; 2) estimate size and frequency of previous shipments, and 3) estimate of outstanding stocks on the market and in your possession.

Sincerely yours,

T. E. Byers, Director  
Office of Compliance  
Bureau of Drugs

Enclosures:

FR 3/24/71

FR 3/25/71

FR 8/25/70

cc: NYK-DO

NYK-DO (NAS/NRC Coord)

BD-313 (NAS/NRC Coord)

BD-300 R/F

CA-226

DHPlumb:tc 3/13/72

Final:tc 6/15/72

Init:ALavender 3/14/72

BEST COPY AVAILABLE

21a

GOVERNMENT EXHIBIT--MAILING RECEIPT.

POST OFFICE DEPARTMENT  
OFFICIAL BUSINESS

POD Form 3811 Apr. 1969 c55-16-71:49-11

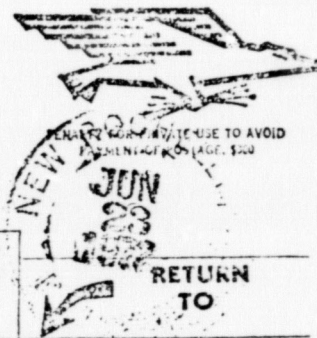
CM32

POSTMARK OF DELIVERING OFFICE

Print your name and address below. If you want to restrict delivery, or to have the address of delivery shown on this receipt check block(s) on other side. Moisten gummed ends and attach this card to back of article.

Donald H. Plumb  
Room 9B-40  
BD-313

DHEW PHS  
5600 Fishers Lane  
Rockville, Maryland 20852






22a

GOVERNMENT EXHIBIT--MAILING RECEIPT.

|                                                                                       |                                                       |
|---------------------------------------------------------------------------------------|-------------------------------------------------------|
| PLEASE FURNISH SERVICE(S) INDICATED BY CHECKED BLOCK(S).<br>REQUIRED FEE(S) PAID.     |                                                       |
| <input checked="" type="checkbox"/> Show to whom, date and address<br>where delivered | <input type="checkbox"/> Deliver ONLY<br>to addressee |

RECEIPT

Received the numbered article described below.

|                           |                                                                                    |                                                                                |
|---------------------------|------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| REGISTERED NO.            |  | SIGNATURE OR NAME OF ADDRESSEE (Must always be filled in)                      |
| CERTIFIED NO.<br>46231    |                                                                                    | SIGNATURE OF ADDRESSEE'S AGENT, IF ANY<br><i>Ronald W. Marotta</i>             |
| INSURED NO.               |                                                                                    |                                                                                |
| DATE DELIVERED<br>6-23-72 |                                                                                    | SHOW WHERE DELIVERED (only if requested)<br>22 Santa Ave<br>New Rochelle 10801 |

GS-16-71615-11 347-105 G.F.

## TRANSCRIPT.

1 gtrm

2 UNITED STATES DISTRICT COURT

3 SOUTHERN DISTRICT OF NEW YORK

4 -----x

5 UNITED STATES OF AMERICA

6 vs.

: 75 Cr. 1200

7 MARCEN LABORATORIES, INC.,  
8 a corporation, and  
9 RAPHAEL MAROTTA, an individual,

Defendants.

10 -----x

11 Before:

12 HON. LLOYD F. MAC MAHON,

13 District Judge

14 January 20, 1976  
15 11:00 a.m.

16 APPEARANCES

17 THOMAS J. CAHILL,  
18 United States Attorney for the  
19 Southern District of New York  
20 BY: LAWRENCE PEDOWITZ, ESQ.,  
21 Assistant United States Attorney

22 JOSEPH ALTIER, ESQ.,  
23 Attorney for defendants.  
24  
25



1 THE CLERK: United States of America vs. Marcen  
2 Laboratories and Raphael Marotta.  
3

4 THE COURT: I am sorry for the delay, gentlemen.  
5 I had a pretrial conference that involved a number of parties  
6 and it took a little longer than I anticipated.

7 MR. ALTIER: Your Honor, for the defendant, the  
8 corporate defendant and the individual defendant, I would  
9 like to make an application.

10 I have been authorized by the corporation and by  
11 the individual defendant to withdraw our plea of not guilty  
12 to the information pending and enter a plea of guilty to  
13 cover the information to certain of the counts, if I may  
14 announce those, your Honor.

15 In the information, for the corporation --

16 THE COURT: Just a minute.

17 All right.

18 MR. ALTIER: For the corporation, and I will say I  
19 was authorized to enter this plea by the president of the  
20 corporation acting in the scope of his capacity as the  
21 president, for the corporation, we wish to withdraw our plea  
22 of not guilty and enter a plea of guilty to counts 21, 22,  
23 24 and 30 of the information.

24 With respect to the individual defendant, we wish  
25 to enter a plea of guilty to count 31 of the information.

1  
2 I have conferred with my client and fully advised  
3 him concerning the penalty both for the corporate client and  
4 individual client, fully advised him concerning the con-  
5 sequences of the plea, all of the legal consequences. I  
6 know your Honor is going to inquire as well, but I did want  
7 to make that representation on the record as well.

8 THE COURT: All right. Will you have the individual  
9 defendant execute this for both himself and the corporation.

10 Is he an officer of the corporation?

11 MR. ALTIER: He is, your Honor. He is President  
12 of the corporation.

13 THE COURT: All right.

14 (Pause)

15 MR. ALTIER: He has signed this individually and  
16 as President (handing).

17 I have a statement of culpability, your Honor,  
18 which we have gone over, which the Assistant U.S. Attorney  
19 and I have gone over which at the appropriate time either  
20 I will read it as an admission or your Honor can inquire  
21 and have my client read it. The only thing is part of it  
22 is in my handwriting.

23 Perhaps if I could read it and he adopts -- he  
24 understands it thoroughly.

25 THE COURT: All right. We will worry about it when



we come to it.

At this point I will just take the plea and I will interrogate the defendant.

THE CLERK: U.S. of America vs. Marcen Laboratories, Inc., a corporation, and Raphael Marotta, an individual.

The U.S. Attorney charges that on or about the dates here and after set forth below in counts 21, 22, 24 and 30, Marcen Laboratories, Inc., a corporation, and Raphael A. Marotta, an individual and President of the corporation, the defendants, in violation of Title 21, U.S. Code, Section 331(d) unlawfully did cause to be introduced and delivered for introduction into interstate commerce at New Rochelle, New York for delivery to the companies described below certain drugs which were new drugs within the meaning of Title 21, U.S. Code, Section 321(p) and were in violation of 21, U.S. Code, Section 355(a) in that No Approval of Applications filed pursuant to Title 21, U.S. Code, Section 355(b) were effective with respect to such drugs.

Count 21.

January 27, 1975, Quaker City Pharmacal Company, Inc., Philadelphia, Pennsylvania, Ossionate Plus.

How do you plead?

THE DEFENDANT: I'm guilty.

THE CLERK: Count 22, January 27, 1975, Quaker City

Pharmacal Company, Inc., Philadelphia, Pennsylvania, Normo-  
tensin, injectable.

How do you plead?

THE DEFENDANT: Guilty.

THE CLERK: Count 24, January 28, 1975, Quaker  
City Pharmacal Company, Inc., Philadelphia, Pennsylvania,  
Viro-Zyme injectable.

How do you plead?

THE DEFENDANT: Guilty.

THE CLERK: Count 30, March 5, 1975, Texas Vitamin  
Company, Dallas, Texas, Lipo-K.

How do you plead?

THE DEFENDANT: Guilty.

THE CLERK: As an individual, count 31, March 5,  
1975, Texas Vitamin Company, Dallas, Texas, Lipo-K capsules.

How do you plead?

THE DEFENDANT: Guilty.

BY THE COURT:

Q Mr. Marotta, I will put this statement to you in  
your capacity both as President of Marcen Laboratories, Inc.  
and as an individual.

Do you understand that?

A Yes, your Honor.

Q I wish to advise you that if you did not plead



2 guilty and if the corporation did not plead guilty to any  
3 count or counts of this information, you or the corporation  
4 -- and wherever I say "you" I mean both you and the corpora-  
5 tion. Do you understand that?

6 A Yes, your Honor.

7 Q You would presume to be innocent under the law.  
8 You would have a right to a speedy and a public trial by an  
9 impartial jury of twelve people or to a trial by the Court  
10 sitting without a jury if you consented.

11 Upon a trial the burden would be upon the govern-  
12 ment to establish your guilt beyond a reasonable doubt to  
13 the satisfaction of all twelve people sitting on the jury  
14 or to the satisfaction of the Court if there were no jury.

15 Upon a trial you would have the right to be silent  
16 and your silence could not be held against you. If you  
17 wished, however, you could take the witness stand and  
18 testify in your own behalf. You would be entitled to see and  
19 hear the witnesses against you and your lawyer would have the  
20 right to cross examine them. You would be entitled to use  
21 the compulsory processes of the Court to compel witnesses to  
22 attend to testify and to obtain documentary evidence which  
23 you wish to offer in your defense.

24 If the Court accepts your plea of guilty you give  
25 up all of these rights with respect to the count or counts

1 upon which you wish to plead and the Court will have the  
2 same power to sentence you as if you had been found guilty  
3 after a trial on that count or counts.  
4

5 Before the Court can accept a plea of guilty, it  
6 must determine whether you are making the plea freely and  
7 voluntarily with an understanding of the nature of the  
8 charges and the consequences of pleading guilty.

9 I want to warn you not to plead guilty unless you  
10 are, in fact, guilty of the charges made against you and the  
11 corporation.

12 Would you state your full name, please?

13 A Raphael Anthony Marotta.

14 Q And how old are you, Mr. Marotta?

15 A 68.

16 Q And what is the extent of your education?

17 A Three years at Columbia College of Pharmacy.

18 Q And where do you live, Mr. Marotta?

19 A 35 Clinton Place, New Rochelle, New York.

20 Q Are you married?

21 A Yes, your Honor.

22 Q Do you live with your family?

23 A My wife.

24 Q Do you have any children?

25 A One. He's in Florida, working in Florida.



1

2

Q And what is your occupation?

3

A Chemist and President of the corporation.

4

Q Do you use narcotics?

5

A No.

6

Q Have you ever used narcotics?

7

A Never.

8

Q Are you now taking any kind of drugs, pills or  
9 medicines?

10

A No, your Honor.

11

Q Are you under the care of a doctor for any condition  
12 at this point?

13

A Only my wife.

14

Q Was Mr. Altier hired by you or was he appointed  
15 by the Court?

16

MR. ALTIER: Hired.

17

A He was hired, your Honor.

18

Q And have you discussed this case with him fully?

19

A Excuse me?

20

Q Have you discussed your case with him here?

21

A Yes, I have, your Honor.

22

Q Has he explained the nature of the charges against  
23 you here?

24

A He has.

25

Q What are the charges against you?

2           A     The fact that I allowed the transportation of new  
3 drugs in interstate commerce.

4           Q     Without the permission of the --

5           A     Without the permission of the Food and Drug  
6 Administration.

7           Q     And you did that on a number of occasions. Do you  
8 understand that?

9           A     That I did that, yes, sir.

10          Q     You and your company?

11          A     Right, your Honor.

12          Q     Did you hear what I just told you about your  
13 Constitutional rights?

14          A     Yes, I did.

15          Q     Did you understand what I have said?

16          A     Yes, I did.

17          Q     And Mr. Altier also advised you of your  
18 Constitutional rights?

19          A     He also explained those to me.

20          Q     And you have signed a written acknowledgement  
21 that you have been advised of your Constitutional rights?

22          A     Right.

23          Q     Is there anything you want to ask me about the  
24 Constitutional rights of yourself or of your company?

25          A     I don't believe so.



1           Q     Do you realize that if the Court accepts your plea  
2  
3 of guilty, your personal plea of guilty, the Court has the  
4 power to sentence you to one year in prison and fine you  
5 \$1000, or both? Do you realize that?

6           A     I have no option, your Honor.

7           Q     Do you realize that?

8           A     I do realize it, sir.

9           Q     And do you realize that if the Court accepts the  
10 corporation's plea of guilty, the Court has the power to  
11 impose a fine of \$1000 on each count or a total fine of  
12 \$4000? Do you realize that?

13          A     I realize that.

14          Q     Do you still want to plead guilty both for yourself  
15 and for the corporation?

16          A     I do.

17          Q     Are you pleading guilty because you are guilty and  
18 for no other reason?

19          A     That is right.

20          Q     Have any promises been made to you that you would  
21 be treated leniently if you pleaded guilty?

22          A     No.

23          Q     Have any threats been made against you?

24          A     No.

25          Q     Have any threats been made against any member of



your family?

A No.

Q Did you cause to be introduced and delivered for introduction into interstate commerce at New Rochelle, New York for delivery to the companies which I will refer to later certain drugs which were new drugs within the meaning of Title 21, U.S. Code, Section 321(p) and were in violation of Title 21, U.S. Code, Section 355(a) in chat No .

Approval of Applications filed pursuant to Title 21, U.S. Code, Section 355(b) were effective with respect to such drugs?

A I did.

Q We turn now to count 21.

Did you and the company on January 27, 1975 cause to be introduced into interstate commerce at New Rochelle for delivery to Quaker City Pharmacal Company, Inc., Philadelphia, Pennsylvania a drug known as Ossionate Plus?

A I did.

Q And is that a drug, Ossionate Plus?

A Yes, your Honor.

Q And was it a new drug?

A Under the statutes, yes, your Honor.

Q And you knew that?

A Yes, your Honor.

2 Q Was this a drug which was not generally recognized  
3 because there was no substantial evidence of its effective-  
4 ness?

5 MR. ALTIER: Within the meaning of the statute.

6 A Within the meaning of that law, yes, your Honor.

7 Q Did you know that there had not been experimentation  
8 by scientists qualified to evaluate its effectiveness?

9 MR. ALTIER: Within the meaning of the statute.

10 A Within the meaning of the statute, within those --

11 Q Did you know that there had been no approval of  
12 the Food and Drug Administration?

13 A Yes, sir, I knew.

14 Q Did you intentionally introduce this item into  
15 interstate commerce, this drug?

16 A Yes, I did.

17 Q Referring to count 22, which is the shipment on  
18 January 27, 1975 to Quaker City Pharmacal Company, Inc.,  
19 Philadelphia, Pennsylvania of Normotensin injectable, would  
20 your answers be the same with respect to that shipment,  
21 that drug as the answers you have given me with respect to  
22 the drug which is the subject of count 21?

23 A Yes, your Honor, the answers would be the same.

24 Q Referring to count 24, which is a shipment of  
25 January 28, 1975, Quaker City Pharmacal Company, Inc.,



1 Philadelphia, Pennsylvania, a shipment of Viro-Zyme inject-  
2 able, would your answers with respect to that shipment and  
3 the drug which is the subject there of count 24 be the same  
4 as your answers to my interrogation on count 21?  
5

6 A Yes, your Honor.

7 Q And referring now to count 30 for a shipment on  
8 March 5, 1975, Texas Vitamin Company, Dallas, Texas of  
9 Lipo-K, would your answers with respect to Lipo-K, this  
10 shipment of March 5, be the same as they were with respect  
11 to the drug involved in count 21?

12 A Yes, your Honor.

13 Q Referring now to count 31, do you individually  
14 admit that on March 5, 1975, you caused to be introduced in  
15 interstate commerce for shipment to Texas Vitamin Company,  
16 Dallas, Texas, Lipo-K capsules? Do you admit that?

17 A Yes, your Honor.

18 Q And would your answers with respect to those  
19 capsules, Lipo-K capsules, be the same as your answers to  
20 count 21?

21 A Yes, your Honor.

22 THE COURT: All right. Do you wish to add anything?

23 MR. ALTIER: No, I don't, your Honor.

24 THE COURT: Do you, Mr. Pedowitz?

25 MR. PEDOWITZ: Yes, your Honor.

2 THE COURT: As to the factual basis?

3 MR. PEDOWITZ: Yes, your Honor, just a few matters.

4 First of all, we request, your Honor, to inquire  
5 of Mr. Marotta whether he agrees that he had a responsible  
6 share in the business process that resulted in the violation  
7 with respect to count 31.

8 BY THE COURT:

9 Q Do you agree you had a responsible share in the  
10 business which resulted in the violation of counts 21, 22,  
11 24 and count 30?

12 A I believe so.

13 Q Well, did you or didn't you?

14 A In count 31.

15 MR. PEDOWITZ: 31, yes, your Honor. That would be  
16 the individual count.

17 Q The individual count.

18 A Yes.

19 Q All right. With respect to count 31.

20 MR. PEDOWITZ: Your Honor, I don't wish to belabor  
21 this and make this a more lengthy proceeding than it has to  
22 be this morning, but in terms, as you know, of the Constitu-  
23 tional claim, I wish to clear up any vagueness attack by  
24 making a record this morning, if that is agreeable with your  
25 Honor.



1 THE COURT: It is perfectly all right. I want to  
2 make a good record here. That is the reason we are going  
3 through all this.

4  
5 MR. PEDOWITZ: Your Honor, I think I will begin  
6 with count 31, which is the individual count.

7 With respect to that count, of course, the drug is  
8 Lipo-K capsules.

9 The claim on the label is that the drug is offered  
10 for treatment of angina pectoris, atherosclerosis and  
11 peripheral vascular diseases in certain cases.

12 Your Honor has heard an adequate explanation --

13 THE COURT: I think, Mr. Pedowitz, as a matter of  
14 proceeding, if you will state what the fact is, then I will  
15 simply ask the defendant whether what you say is sub-  
16 stantially true.

17 MR. PEDOWITZ: Fine, your Honor.

18 THE COURT: I think that would make a better  
19 record here. If you wish to add something to inform me, all  
20 right, fine.

21 MR. PEDOWITZ: Your Honor, we would call as an  
22 expert witness with respect to this drug and the drug in  
23 count 30 Norton Spritz, who is the Chief of Medical Services  
24 at the Manhattan Veterans Administration Hospital, and he  
25 is a professor of medicine at the New York University School

1 of Medicine, and he would testify that none of the references  
2 cited in the labeling of Lipo-K drugs reports on an adequate  
3 and well controlled study involving the use of Lipo-K  
4 drugs upon which experts could conclude that either Lipo-K  
5 drugs is safe and effective under the conditions of use  
6 stated in the labeling.  
7

8 THE COURT: Mr. Pedowitz, I'm afraid I didn't make  
9 my point.

10 Not what somebody would testify to, what fact that  
11 we need an admission on from this man, what fact that I have  
12 not covered.

13 MR. PEDOWITZ: Very well, your Honor.

14 Your Honor, would the defendant, therefore, admit  
15 that there are no adequate and well controlled studies of  
16 which he is aware as that term is defined in the CFR, which  
17 would indicate that the drugs contained in the counts for  
18 which he as an individual and the corporation have pleaded  
19 guilty this morning exist, that is, that there are no such  
20 tests?

21 MR. ALTIER: We would admit, your Honor, that  
22 there are not the tests as outlined --

23 THE COURT: Not you, does he admit?

24 MR. ALTIER: Yes, yes.

25 May I phrase it, your Honor?



1 gtrm  
2 THE COURT: Please. I thought, Mr. Pedowitz,  
3 I covered that point.

4 MR. ALTIER: We had covered it.

5 MR. PEDOWITZ: Your Honor, I would like to make  
6 this perfectly clear that there are no tests of which he  
7 is aware.

8 THE COURT: But I put to him that there has not  
9 been any experimentation by scientists qualified to evaluate  
10 the effectiveness of this drug.

11 MR. PEDOWITZ: Your Honor, in point of fact, we  
12 are aware of certain reports, but we don't view them as  
13 adequate and well controlled as defined in the CFR.

14 THE COURT: All right. State your facts.

15 This record is going to be one horrible mess  
16 already. I tried from your brief, Mr. Pedowitz, to pick  
17 out the four salient factors for the basis of a plea of  
18 guilty.

19 MR. PEDOWITZ: Yes, your Honor.

20 THE COURT: Go ahead. State what other facts you  
21 want me to ask the defendant whether these are substantially  
22 true.

23 MR. PEDOWITZ: Well, your Honor, is it a fact that  
24 he agrees that there are no adequate and well controlled  
25 tests?

2 THE COURT: You state them as facts and then  
3 I will put them to the defendant whether it is true what  
4 you said.

5 MR. PEDOWITZ: Your Honor, the government is  
6 prepared to prove as a fact that there are no adequate and  
7 well controlled tests as that is designed in the CFR.

8 THE COURT: Please. I do not care what you are  
9 prepared to prove. State it as a fact.

10 MR. PEDOWITZ: Your Honor, we are prepared to  
11 prove as a fact that there are no adequate and well  
12 controlled tests as that is designed in the CFR and we  
13 would like to have Mr. Marotta's admission to that effect.

14 THE COURT: I do not see how he can admit that  
15 you are prepared to prove it.

16 State it as a fact.

17 MR. PEDOWITZ: Your Honor, there are no adequate  
18 and well controlled tests as that is designed in the CFR.

19 THE COURT: Do you admit that?

20 THE DEFENDANT: I admit there are no adequate  
21 proofs as stated in the Code of the FDA.

22 THE COURT: Do you admit what the prosecutor  
23 just said? Yes or no?

24 THE DEFENDANT: Yes.

25 THE COURT: All right. What else do you want?



MR. PEDOWITZ: Your Honor, moving through the counts one at a time, with respect to count 21, there was a seizure in 1967 with respect to Ossionate Plus injectable by the FDA. There was also a seizure in 1969 with respect to this particular drug and, in addition, in 1971 and 1973 there were two Section 305 hearings as that is designed in the statute -- it is actually 335 in Title 21 -- which preceded a recommendation to the U.S. Attorney that criminal prosecution be brought.

We would like Mr. Marotta's admission to that fact.

THE COURT: Is what counsel just said true, substantially true?

THE DEFENDANT: Yes, your Honor.

MR. PEDOWITZ: With respect to count 22, your Honor, of the Normotensin, in 1967, there was a seizure of this particular drug, there was a default decree entered in 1968. There was also a second seizure in 1967 for which a claim was answered and then withdrawn and a defaulted --

THE COURT: A seizure from these defendants?

MR. PEDOWITZ: Yes, from this particular defendant, your Honor, of this drug.

There was also, your Honor, a Section 305 hearing in 1973.

1 gtrm

2 MR. ALTIER: Your Honor, I would have no objection  
3 to my client admitting that, but in fairness and in fullness,  
4 I would like to put in the actual stipulation that was  
5 inserted in that. We have that.

6 THE COURT: I can't do that. I am taking a  
7 plea of guilty.

8 Your client either has to admit or deny the  
9 facts which constitute this crime. That is what the  
10 Federal Rules require.

11 MR. ALTIER: I understand.

12 THE COURT: I think this is a silly rule, because  
13 it is just about as easy to try somebody as to go through  
14 this, but I don't make the rules.

15 Now, that's it, either that or a trial. I don't  
16 care which.

17 MR. ALTIER: Would your Honor put that question  
18 and my client will answer it, your Honor?

19 THE COURT: State what he said.

20 MR. ALTIER: Mr. Marotta, did you hear what the  
21 U. S. Attorney just said?

22 THE DEFENDANT: Yes.

23 THE COURT: And is it true?

24 THE DEFENDANT: Yes, sir.

25 MR. PEDOWITZ: With respect to count 24, the



Viro-Zyme injectable count, it was with respect to this drug a seizure in 1969, which a defaulted decree was entered in Texas, and there were Section 305 hearings in 1971 and in 1973. There was also a 1975 seizure, but that is still pending.

THE DEFENDANT: That's true.

THE COURT: Is that true?

THE DEFENDANT: That's true.

MR. PEDOWITZ: With respect to count 30, Lipo-K injectable, there was a seizure in 1967 and two seizures in 1975 and there was a 305 hearing in 1973.

THE DEFENDANT: That is true.

THE COURT: Is that true?

THE DEFENDANT: That's true.

MR. PEDOWITZ: In each of those cases, a defaulted judgment was entered.

With respect to count 31, your Honor, which is the count for which this defendant is pleading guilty as an individual, there was, in 1973, a Section 305 hearing. In addition, as your Honor may recall from our last conference, there was a filing in the Federal Register in 1970 indicating that with respect to methionine and choline, which are compounds contained in this drug, that the FDA was considering withdrawing any approvals it had with respect to related

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drugs.

In 1971 it entered in the Federal Register a notice that all approvals were being withdrawn with respect to methionine and choline and that was, in fact, done.

Then in 1972 a letter was sent to Mr. Marotta, for which we believe we have a signature of Mr. Marotta -- there is a return September signed by a Raphael A. Marotta -- and in that letter Mr. Marotta and Marcen Laboratories were advised of the action taken by the FDA.

THE COURT: Is that substantially true?

THE DEFENDANT: That's right.

MR. PEDOWITZ: Your Honor, that completes any presentation which the government has.

THE COURT: All right. The Court will accept the plea.

You will be advised as to the date of sentence. There is no point in setting a date at this point until we determine the Constitutionality of the statute.

MR. ALTIER: Fine, your Honor.

THE COURT: All right?

MR. PEDOWITZ: Your Honor, I believe you have a stipulation indicating --

THE COURT: I do and I have signed it.

MR. PEDOWITZ: Fine, your Honor.



2 I appreciate your cooperation, gentlemen, in  
3 helping to work this out in a practical way.

4 I have kept a copy so I will have it as a form  
5 for some later day.

6 MR. PEDOWITZ: Thank you very much.

7 MR. ALTIER: Your Honor, may the defendant be  
8 continued in his own recognizance?

9 THE COURT: Yes.

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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA :

- against - 75 Cr. 1200

MARCEN LABORATORIES, INC., :  
a corporation, and :  
RAPHAEL A. MAROTTA, :  
an individual, :

Defendants. :

- - - - -x

B e f o r e:

HONORABLE LLOYD F. MacMAHON,

District Judge.

New York, New York  
July 27, 1976 - 11:30 a.m.

A p p e a r a n c e s:

ROBERT B. FISKE, JR., Esq.  
United States Attorney for the  
Southern District of New York  
BY: LAWRENCE PEDOWITZ, Esq.  
Assistant United States Attorney

BROMSEN, GAMMERMAN, ALTIER & WAYNE, Esqs.  
Attorneys for Defendants  
BY: IRA GAMMERMAN, Esq., of Counsel.



MR. PEDOWITZ: Ready for the government, your Honor.

MR. GAMMERMAN: Ready for the defendant, your Honor.

THE COURT: Proceed.

All right, Mr. Pedowitz, I will hear the government.

MR. PEDOWITZ: Your Honor, the government has nothing to say.

THE COURT: Thank you. Mr. Gammerman.

MR. GAMMERMAN: If your Honor please, I have had an opportunity to read the presentence report, and I would just like to highlight one or two points raised in that report.

The defendant, as you know, is a 69-year-old man. This is his first criminal involvement. The report indicates quite accurately the health situation of his wife, who is dependent upon him for not just emotional, but physical assistance in the home. They live together.

I ask your Honor to take the defendant's age, the circumstance of his life up to the point of this case, the health situation with respect to his wife, who is unaware of these criminal proceedings, into consideration, and all the other factors raised in the presentence report,

in sentencing this defendant.

THE COURT: Do you have anything to say for yourself, Mr. Marotta, before the Court pronounces sentence upon you and upon your company?

THE DEFENDANT: I believe the attorney has mentioned everything that can be said. On behalf of the company, why, the company is being disorganized. The corporation is being dissolved. There are no drugs available. Whatever is there is being sold.

THE COURT: Have you verified that? Is this company going out of business?

MR. PEDOWITZ: That was my understanding before the plea, your Honor, and I have no reason to disbelieve Mr. Marotta's representation.

THE COURT: All right. Mr. Marotta. I didn't mean to interrupt you. Do you have anything further to say?

THE DEFENDANT: No..

THE COURT: Mr. Marotta, there was a persistent, stubborn, even defiant violation on your part. Drugs are products which require close supervision in the interest of the national health and welfare. To insure that, Congress has created the Pure Food and Drug Laws, and has put them under the administration of Food and Drug



Administration, and if those laws are to be successful in their goal of protecting the public health and safeguarding people from dangerous drugs, they must be complied with. They cannot be ignored. They cannot be flaunted. That certainly wasn't the case here on your part.

I am mindful of your age and of your wife's health. Nevertheless, the Court must look to the public welfare. Accordingly, the Court sentences you to ten days in jail and fines you \$1000. One count 31.

The Court in the case of Marcen Laboratories, Inc., fines Marcen Laboratories \$1000 on count 21, \$1000 on count 22, \$1000 on count 24, and \$1000 on count 30, the sentences to be consecutive for a total fine of \$4000.

As an officer of that company you are to stand committed until the fines are paid both for the company and for yourself. It is my duty to advise you that you have a right to appeal this conviction.

This is a plea. You stipulated here, didn't you?

MR. PEDOWITZ: Yes.

THE COURT: In accordance with your stipulation that if you wish to appeal it that you must file a notice of appeal within ten days.

MR. GAMMERMAN: Can we have a stay of the

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sentence, your Honor, pending the decision on whether or not  
to file an appeal?

THE COURT: Any objection?

MR. PEDOWITZ: None, your Honor.

THE COURT: Execution of the sentence is stayed  
pending appeal.

MR. GAMMERMAN: Thank you, your Honor.

MR. PEDOWITZ: Thank you, your Honor.

- - -



jgs

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,

Plaintiff,

vs.

75 Cr. 1200

MARCEN LABORATORIES, INC., a  
corporation and RAPHAEL A.  
MAROTTA, an individual,Defendants.  
-----X

Before:

HON. LLOYD F. MacMAHON,

District Judge.

New York, January 16, 1976;  
10.30 o'clock a.m.

## APPEARANCES:

THOMAS J. CAHILL, Esq.,

United States Attorney  
For the Government

BY: LAWRENCE B. PEDOWITZ, Esq.,

Assistant United States Attorney

and

GARY YINGLING, Esq., and  
DON BEERS, Esq.,Attorneys, U. S. Health, Education &  
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and

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Compliance Office,  
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2 BROMSEN, GAMMERMAN, ALTIER and WAYNE, Esqs.,  
3 450 Seventh Avenue  
4 New York, N. Y. 10001

5 BY: JOSEPH P. ALTIER, Esq.,  
6 Of Counsel.

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8 MR. ALTIER: Ready on the motion, your Honor.

9 MR. PEDOWITZ: The Government is ready, your  
10 Honor.

11 THE COURT: Proceed.

12 MR. ALTIER: Your Honor, as you offered a  
13 few days ago when the case was on, I called your office  
14 and put the case on for a motion this morning. It was  
15 my hope, No. 1, to clear your Honor's calendar and to  
16 advise your Honor that Tuesday there would be no trial,  
17 or next week there would be no trial. I saw no need  
18 for it.

19 The facts in the case, that is, the mechanical  
20 facts, would be tedious to prove and they are not really  
21 in dispute. My client has had his books open to Food  
22 and Drug. They know when, where and how he has shipped  
23 over the many, many years that he has been in the business,  
24 with these particular pharmaceutical items.

25 So that truly there is no factual issue there  
with respect to many of the items that we are talking about,



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2 or certainly enough of the items to make it relevant  
3 for sentence purposes. My client did transport in  
4 interstate commerce some of these items as alleged in the  
5 complaint.

6 And, in the event that your Honor upholds the  
7 constitutionality of this statute, we are willing to plead  
8 to certain of those, and we have already spoken to the  
9 Government about that, certain clear counts that will  
10 cover the matter.

11 The reason why I am here, as a lawyer, is that  
12 as I read a statute, that is, both a civil and a criminal  
13 statute, its applicability can go civilly and it can also  
14 go criminally, the same statute can go either way.

15 I have reviewed it, looked at it, am familiar  
16 with it civilly, and familiar with the many, many cases  
17 under it civilly, defining it constitutionally, et cetera,  
18 but I haven't been able to find a case, nor have I been  
19 advised of any case, involving the criminal statute, the  
20 criminal aspect of it, where a man can go to jail because  
21 of it.

22 Therefore I cannot recommend to my client a  
23 straight plea to this statute which I, in reviewing the  
24 thing, have serious constitutional questions about.

25 My remedy, therefore, is to present that

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2 problem, that isolated problem, to your Honor for your  
3 Honor's decision with the hope that your Honor will agree  
4 with me on the lack of constitutionality of this statute  
5 as a criminal statute and, if not, the right to preserve  
6 it and to present it to my client and to proceed after  
7 a plea.

8 THE COURT: I just have one question I want  
9 to you at this point.

10 Is it your contention that this statute, or  
11 this scheme here which refers you one to another, is  
12 facially unconstitutional or is it your point that it is  
13 unconstitutional as applied here?

14 MR. ALTIER: Facially, your Honor.

15 THE COURT: All right.

16 MR. ALTIER: That is precisely the point, your  
17 Honor, just on its face.

18 If I can just cite United States v. Brewer,  
19 139 U.S. 278, this is really the thrust of my problem with  
20 this statute, and it is a very brief quote:

21 "There is a constitutional requirement that  
22 a statute 'must be informative on its face and so  
23 explicit that all men subject to its penalties may  
24 know what acts it is their duty to avoid.'"

25 Your Honor, 331 is the criminal statute.



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2 We looked at that the other day, and it really says the  
3 following acts are unlawful:

4 (d) the introduction in interstate commerce  
5 of an article in violation of Sections 344 and 345.

6 The person accused must now go to 334 and 345.  
7 Let me oversimplify those sections. They say, if you  
8 have a new drug, you have a duty to make a new drug  
9 application to the Food and Drug Administration, and this  
10 is the way you do it. That is 345, and they prescribe  
11 the way to do it.

12 And now comes the real problem, because it is  
13 confusing at that point. But now they get ready to  
14 define what is a new drug.

15 What is a new drug that makes it a crime if you  
16 ship this and don't go through this application? What is  
17 a new drug? And they define it as follows, and here  
18 is where I suggest that it is fatally vague, the statute  
19 itself is fatally vague.

20 A new drug is defined in 321(p) as  
21 "any drug the composition of which is such that  
22 such drug is not generally recognized by experts  
23 qualified by scientific training."

24 This defendant, this fellow, who has been  
25 distributing pharmaceutical items since 1935, is faced with

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2 the test for criminality. We know constitutionally it  
3 must be specific, and the test and the definition of the  
4 crime itself is a word that is absolutely opposite to the  
5 word "specific," which is "general." And not only is it  
6 general, the definition of the crime, it is flip a coin  
7 general, but generally recognized.

2 8 Now, we not only go from the amorphous word  
9 "general" in this brand new, yet unused criminal statute,  
10 we go to "generally" and then "subjective" and then  
11 "experts."

12 We litigious people involved with litigation  
13 know what kind of a test, bing, bang, we can get into when  
14 we get into experts and expert testimony. It is sub-  
15 jective. The test is subjective. The test is  
16 general.

17 I'm suggesting that Congress, the United States  
18 Congress, was clearly in error when it passed this as a  
19 criminal statute.

20 I am aware that there are many, many civil  
21 cases which Food and Drug has gone through and they have  
22 defined it and they have said what is generally recognized  
23 and they put experts on the stand and there are battles  
24 of experts. I don't know whether it is fine, but I'm  
25 not quarreling with it in a civil case. Where I am



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2 quarreling with it is in a criminal case.

3 I am also aware, your Honor, that the United  
4 States Congress has, in different kinds of cases, for  
5 example drug cases, and by that I'm talking about dangerous  
6 drug cases, said we are proscribing dangerous drugs, and  
7 we know the word "dangerous" is somewhat vague and we are  
8 giving to the Food and Drug authorities the power, with  
9 all their research facilities and everything else, to  
10 define what is a dangerous drug.

11 The United States Congress did that in that case  
12 and it has been held throughout the whole string and field  
13 of cases. But the United States Congress did not do that  
14 in this case. What the United States Congress did in  
15 this statute was it left it up to experts, just general  
16 experts. We can bring them in from the lay field, any  
17 field we want to bring them in from, and then the test is,  
18 if they generally agree, subjectively, then this is a  
19 proscribed drug.

20 I am suggesting that a defendant is not given  
21 any warning of proscription by the face of such statute.  
22 The face of such statute is unconstitutional. I am not  
23 arguing about warnings, whether Food and Drug advised this  
24 fellow that it was their feeling that this was a new drug  
25 and it was not protected by any of the language here.

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2 And my fellow through the years has said, "Oh, no.

3 I bought this way back and it is an old drug." Okay.

4 It is sort of like the rooster saying -- this  
5 is a bad example, but this is my client, I'm talking about  
6 the defendant, saying, "Just because the rooster crows and  
7 thinks that because he crows the sun comes up, that is not  
8 why the sun comes up."

9 Just because Food and Drug says it is a new  
10 drug doesn't make it a new drug.

11 So that we've had this issue civilly going.  
12 But while we are addressing ourselves to a criminal statute,  
13 I have not been advised of any test, we are having a  
14 de novo, first blush looksee at this thing, as far as I  
15 know, and I am suggesting, your Honor, praying that you  
16 decide and review this matter and that you agree with me  
17 on this issue and strike this statute as being constitution-  
18 ally vague.

19 THE COURT: Isn't there a line of cases holding  
20 that if the defendant knows what the statute means that the  
21 vagueness problem is avoided?

22 MR. ALTIER: Your Honor, I don't know of that  
23 line of cases. But I don't know what this statute means.  
24 I don't think, reading this statute, you can define what  
25 it means. We are talking criminally now. It has never



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2 been tested criminally. And when you read a statute,  
3 you've got no cases to go on. I am advising him, you  
4 know.

5 THE COURT: But I think there is such a line  
6 of cases that, if he knows, if he knows, that's enough.

7 I could be wrong. It is my recollection from  
8 a similar problem from when I practiced law.

9 MR. PEDOWITZ: That is our understanding also,  
10 your Honor.

11 MR. ALTIER: My point here is, if it is uncon-  
12 constitutionally vague on its face, he can't know.

13 THE COURT: But the answer to it is he does.  
14 If he knows, that's it. I had the problem years ago on  
15 what constituted merchandise the origin of which was China,  
16 and it was the same kind of problem. If you bought a  
17 Ming vase in England that had been in a museum there for  
18 200 years, was the origin China because somebody in  
19 England had brought it from China hundreds of years ago?

20 I was satisfied after research that the argument  
21 for vagueness wasn't much good, but I tried it out on Judge  
22 Raphael and he didn't think it was much good either.

23 MR. ALTIER: I think the argument here is a  
24 little better than that.

25 THE COURT: It certainly is not frivolous, no.

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2 I appreciate your making the argument, because it is a  
3 problem we have and we have to clear it up.

4 MR. ALTIER: Thank you, your Honor.

5 THE COURT: Mr. Pedowitz?

3 6 MR. PEDOWITZ: Yes, your Honor. We are, of  
7 course, of the view that your Honor ought to decide this  
8 issue. Indeed, the Government, frankly, would welcome  
9 a decision as to the constitutionality of this statute.

10 It has in fact been construed once in a criminal  
11 context. The case, however, is not reported in F. Supp.,  
12 and that no doubt is the reason Mr. Altier has not found it.

13 It is a Northern District of Michigan case,  
14 and it is in fact reported in the Federal Food, Drug and  
15 Cosmetic Act Reporter, and I'll be very happy to supply  
16 both the Court and counsel with a copy of it.

17 Your Honor, our view of this issue is slightly  
18 different than Mr. Altier's. It begins with the premise  
19 that a statute which appears to be facilly vague can  
20 avoid a vagueness attack by two methods.

21 First, the statute can have been construed by  
22 a higher court or by a court of the land, which thereby  
23 narrows the statute and the vagueness problems are avoided.

24 Secondly, a defendant can, as your Honor has  
25 pointed out, know full well that his conduct within the



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2 core area of the statute, even though the statute on its  
3 fringes may be vague.

4 Your Honor, we think in this case the statute  
5 has been sufficiently narrowed both by the Supreme Court  
6 of the United States and by other courts, and in addition  
7 this defendant could have had no doubt whatsoever that he  
8 was within the core area of this statute.

9 First, your Honor, in terms of those cases  
10 which your Honor was alluding to, there are recent opinions.  
11 Parker v. Levy was a construction of the Code of Military  
12 Conduct in the Supreme Court of the United States. We only  
13 have the Supreme Court cite. It is 94 Supreme Court  
14 2547. Of course, your Honor, we will be very happy to  
15 supply you with a memo on this particular issue, which will  
16 be far more extensive than my verbal presentation.

17 In addition, Smith v. Gogoen, which talked  
18 about vagueness in terms of First Amendment cases recently,  
19 and that is reported in 415 U.S. 566.

20 That case indicated, in the First Amendment  
21 area, that while a defendant who is in the core of a statute  
22 which may arguably be vague may have standing to challenge  
23 the statute, in any other area but the First Amendment area  
24 the defendant must be able to show that he is not in fact  
25 within that core area.

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2 This case, being a case of a business regulatory  
3 statute, is governed by the principle of United States v.  
4 Mazurie, which was reported in 95 Supreme Court 710, and that  
5 is a 1975 statute which says that it is well established  
6 that vagueness challenges of statutes which do not involve  
7 First Amendment freedoms must be examined in the light of  
8 the facts of the case at hand.

9 Turning to the construction of this statute, we  
10 agree that, looking at the deposition of "new drug" in  
11 Section 321(p) of the U. S. Code Annotated, there is no  
12 doubt, looking at that statute for the first time, that one  
13 could construct it as vague. We hardly disagree with  
14 that.

15 However, that statute has been construed  
16 authoritatively by the Supreme Court of the United States,  
17 admitted in a civil proceeding. However, there is no  
18 principal of which I am aware that says that a statute  
19 cannot be narrowed in a civil proceeding also. The defend-  
20 ant thereby understand that a new drug is being redefined.

21 Now, in this Supreme Court case, Weinberger v.  
22 Hynson, 412 U.S. 609, which is a 1973 decision and a  
23 decision which certainly preceded the acts for which we  
24 wish to hold this defendant responsible, the Supreme  
25 Court indicated that the generally recognized definition



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2 of "new drug" must be defined in terms of Section 355(d),  
3 which discusses "substantial evidence."

4 Now, in effect what that provision says is that  
5 a drug will not be viewed as, generally recognized as  
6 effective unless an applicant can point to controlled  
7 scientific tests that have been performed with respect to  
8 that drug specifically that show that the drug is  
9 effective.

10 The Supreme Court couldn't have been clearer  
11 about that in reading 355 to go with 321.

12 THE COURT: But in a criminal context, Mr.  
13 Pedowitz, might not that shift the burden of proof?

4 14 MR. PEDOWITZ: There is no doubt, your Honor,  
15 that we would have to prove beyond a reasonable doubt that  
16 the drug is generally recognized by experts as effective,  
17 by experts who are qualified in this area.

18 In defining that provision, your Honor would  
19 be obliged to charge the jury -- I wish to quote, your  
20 Honor, so that I am not misleading the Court in any  
21 respect -- that they must find beyond a reasonable doubt,  
22 and I am now quoting from Section 355(d), which defines  
23 substantial evidence:

24 "That there are adequate and well controlled  
25 investigations, including clinical investigations

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2 by experts qualified by scientific training and  
3 experience to evaluate the effectiveness of the  
4 drug involved, ..."

5 In other words, perhaps I've misdefined that,  
6 but you would be obliged to charge the jury that they must  
7 find beyond a reasonable doubt that there are not adequate  
8 and well controlled investigations, including clinical  
9 investigations, by experts qualified by scientific train-  
10 ing and experience which should that the drug is effective.

11 In other words, if the criteria by which --

12 THE COURT: You mean the absence of any such  
13 investigations, the lack of any such investigations.

14 MR. PEDOWITZ: Precisely.

15 THE COURT: Because that would be up to the  
16 Government. They would have to prove that.

17 MR. PEDOWITZ: That is correct. We would,  
18 in essence, have to prove the negative.

19 THE COURT: Hardly an idea criminal statute.

20 MR. PEDOWITZ: That is correct, your Honor.

21 In addition to the constructions which have  
22 been placed on the statute, not only by the Supreme Court  
23 but by other lower courts, there are the facts in this  
24 case. This defendant is not a defendant who is totally  
25 unaware of the fact that his drug is being characterized



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2 as a new drug. Indeed, if I were to point specifically  
3 to the facts with respect to each count, they would  
4 show that this defendant on a number of occasions had  
5 drugs seized which were traveling in interstate commerce.  
6 They were seized by the Federal Drug Administration.

7 Thereafter there were forfeiture proceedings  
8 conducted with respect to the drugs. In some cases the  
9 defendant filed answers claiming that the drugs were  
10 grandfather clausued, which I thi.k your Honor is familiar  
11 with to come degree from the prior discussions. But the  
12 defendant seems to have abandoned the grandfather clause  
13 argument. The defendant seems to have withdrawn that  
14 claim and has defaulted. This has happened with respect  
15 to every drug that is included within this particular  
16 information.

17 In addition, we have a filing by the FDA of  
18 a notice in the Federal Register with respect to at least  
19 one of the drugs, this one being the one which we expected  
20 the defendant to plead to, Count 31 of the information, a  
21 filing in the Federal Register that the component part  
22 of the drug which was in issue in that count is in fact a  
23 new drug.

24 Notice was given to the public and to those  
25 interested persons who wished to file that they should

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2 contest that if they desired to contest it. There was  
3 no contest made by Mr. Marotta nor by Marcen Laboratories.

4 Subsequently, after a hearing before the FDA,  
5 a notice of withdrawal was filed in the Federal Register  
6 which told those companies that was specifically included  
7 in the hearing that the drug that they were dealing with  
8 was in fact a new drug, and approval by the FDA was with-  
9 drawn as to distribution of that drug in interstate  
10 commerce.

11 It is clear from the Code of Federal  
12 Regulations that the defendant was affected by that  
13 decision, because he had a similar compound drug and he  
14 was noticed that he should have participated in that  
15 proceeding if he desired to contest it. He was thereby  
16 affected by the agency decision.

17 Subsequently the agency did not only rely on  
18 the fact that he was obliged by the Code of Federal  
19 Regulations to take notice of that fact, but they sent him  
20 a letter. They told him that the drug which he was  
21 distributing -- and this is a letter in 1973, prior to the  
22 dates of these transportations, indeed of the ones we are  
23 talking about one is March 5, 1973, he was told specific-  
24 ally by letter, return return requested, and he signed  
25 it -- was a new drug, that the agency had determined it



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2 to be such, that fact had been published in the Federal  
3 Register, and he should not distribute in interstate  
4 commerce. But he went ahead and did it.

5 Your Honor, the cases make clear, namely  
6 Parker v. Levy and United States v. Mazurie, which I cited  
7 before, that the constitutionality of a statute must be  
8 viewed, if it is in a business regulatory context, in  
9 terms of the specific facts of each case.

5 10 Now, if this defendant is claiming that he  
11 didn't know that he had a new drug on his hands, he is  
12 absolutely wrong. He could not be misleading the Court  
13 more. He knew that he had a new drug on his hands, that  
14 the FDA considered it as such, and to say that he didn't  
15 know enough about what the statute said to be able to guide  
16 his conduct we think is a frivolous argument.

17 And, your Honor, I don't want to belabor this  
18 point, but we are certainly prepared to give you document-  
19 ation with respect to each count in terms of this defendant's  
20 violations of the FDA regulations and publication in the  
21 Federal Register, and we will augment our arguments this  
22 morning with citations to specific cases and constructions  
23 of the statute.

24 THE COURT: I would like a memo, obviously, but  
25 I have another specific question I want to ask you, Mr.

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2 Pedowitz.

3 How do we establish a factual basis for a plea  
4 of guilty, if the defendant chooses to do it?

5 MR. PEDOWITZ: Your Honor, indeed, we have  
6 prepared, in case the defendant was going to plead this  
7 morning, a statement by the Government as to facts we  
8 would be prepared to prove. We are in fact prepared to  
9 prove, with respect to the new drug issue, that we would  
10 put scientists on the stand, very eminent scientists in the  
11 New York area, who would testify that their view of the  
12 effectiveness of this drug is that it is not generall  
13 recognized as effective for the purposes prescribed in  
14 the label.

15 Indeed, their view is that it would be, in at  
16 least one case, like drinking water. That is the degree  
17 of effectiveness of this particular drug. It is totally  
18 ineffective.

19 And their view would be that among their  
20 colleagues, very eminent physicians and doctors of  
21 pharmaceutical sciences, that these drugs are simply not  
22 effective. And that is the general recognition of their  
23 group.

24 In terms of the other elements of the crime,  
25 we would of course be prepared to prove that the drugs were



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2 in fact shipped in interstate commerce. We have the  
3 invoices. We can also prove that it is a drug within  
4 the definition of "drug" also contained in Section 321,  
5 and I think that would just about do it.

6 THE COURT: How do you prove that he knew?

7 MR. PEDOWITZ: His knowledge, your Honor, is  
8 not, to my understanding, in issue. So long as he  
9 substantially controls the corporation, as is the case  
10 here since he is the sole stockholder and owner of the  
11 corporation --

12 THE COURT: No, no. I meant, to avoid the  
13 vagueness point, how do you show that he knew?

14 MR. PEDOWITZ: I don't believe that specific  
15 knowledge is a requirement in this type of statute.

16 THE COURT: You think constructive knowledge  
17 is enough? What you've been arguing is constructive  
18 knowledge: publication in the Federal Register, et cetera.

19 MR. PEDOWITZ: Certainly the letter went  
20 directly to him.

21 THE COURT: The letter went directly to him.

22 MR. PEDOWITZ: And he signed the return receipt.  
23 We have that letter and the return receipt. I don't have  
24 handwriting exemplars, so in the absence of securing them  
25 I couldn't prove beyond a reasonable doubt today that he

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2 did in fact sign it. But I expect that, since his  
3 signature is on it, or his name is on it, that he did in  
4 fact receive it. It was certainly sent to him.

5 That I think would probably be sufficient to  
6 impute knowledge to him with respect to that one particular  
7 drug.

8 But my view is, and concededly this is prelim-  
9 inarily, because I haven't sat down and read the cases  
10 again, but I remember the Dotterweich case in the Supreme  
11 Court, which goes back some time into the '40s, I think,  
12 which talks about the fact that in a business regulatory  
13 context the defendant need not be shown to have had actual  
14 knowledge; all he need in fact have done is distribute a  
15 drug which is a new drug, he need not know that it is in  
16 fact a new drug.

17 I am informed, your Honor, by counsel for  
18 HEW and the FDA, Mr. Yingling, who was kind enough to come  
19 up from Washington this morning, that in fact there are more  
20 recent cases. We will be very happy to cite those in our  
21 memorandum, too.

22 THE COURT: Off the record.

23 (Discussion off the record.)

24 THE COURT: Why don't you work out a written  
25 stipulation that does what you want to do and I'll go ahead



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2 and rule on it. But I would like memoranda from you.

3 MR. PEDOWITZ: Certainly, your Honor.

4 THE COURT: When are you going to do that?

5 You are going to work on a stipulation that will permit us  
6 to go forward with a plea on Tuesday and permit me to  
7 reserve on this rather complex constitutional law problem  
8 and also will preserve the defendant's right to appeal  
9 from whatever my decision may be, provided I hold that it  
10 is --

11 Can the Government appeal?

12 MR. PEDOWITZ: Yes, your Honor. I think what  
13 your Honor can do then is vacate the plea, dismiss the  
14 indictment, and then we could have an appeal from that.

15 THE COURT: All right.

16 MR. ALTIER: May I just be heard in reply to  
17 Mr. Pedowitz?

18 THE COURT: Surely.

19 MR. ALTIER: Your Honor, there is no question,  
20 and we'll be ready to so stipulate, that Mr. Marotta  
21 knew that the FDA felt that these were new drugs.

22 Now, I am making a general statement, but every  
23 time the FDA said that this is a new drug, there was a  
24 reply to such letter saying, "Like fun it is a new drug.  
25 We've had it on the market since 1935 or so. If we can do

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2 anything to cooperate with you, o help you, fine. But  
3 it is our position that it is not a new drug."

4 We know that the rooster kept saying, "The sun  
5 comes up because I say it comes up." But it has been  
6 our contention all along that this is not a new drug and  
7 that "You are wrong, Food and Drug."

6 8 So I didn't want that to go by. Yes, there  
9 was a notice to us that that was their feeling. But there  
10 was a notice right back saying, "Oh, no, it is not a new  
11 drug."

12 THE COURT: You say it doesn't make it so  
13 because they say it.

14 MR. ALTIER: Precisely right. And it wasn't  
15 that we ignored it. We continued to say, "We don't  
16 agree with you."

17 MR. PEDOWITZ: We don't disagree with that  
18 either, your Honor. Our view is simply that if this  
19 defendant is going to argue to this Court that he didn't  
20 know enough to guide him his own conduct so as to stay  
21 outside the scope of the statute, we think that is pre-  
22 posterous since the FDA had already told him at an  
23 administrative proceeding that they had determined this  
24 was in fact a new drug.

25 Counsel may have claims which he views as at



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2 least colorable that it is in fact not a new drug, that  
3 it is an old drug. But that, your Honor, doesn't, in  
4 our view, take it outside the statute.

5 THE COURT: But does it pose an issue of fact  
6 for resolution in a trial court? And if so, how do we  
7 go about resolving it? That is what troubles me. That  
8 is why I posed this problem, because it seems to me that  
9 these were not suitable questions for a jury.

10 MR. PEDOWITZ: That involves a number of complex  
11 issues. We thought about them, certainly, and we dis-  
12 cussed them, but we would have to sit down and really  
13 draft requests to charge before we authoritatively wanted  
14 to commit ourselves.

15 But I do want to point out that in the appendix  
16 decisions, in the same volume of Supreme Court reports as  
17 412 the Supreme Court of the United States said that what  
18 the FDA said was a new drug was a new drug so long as there  
19 was adequate opportunity to review it in the Court of  
20 Appeals through administrative review.

21 In this particular case, with respect to this  
22 drug contained in Count 31, the FDA determined that that  
23 drug was in fact a new drug. An opportunity was given to  
24 all those who had intervened or wished to intervene to  
25 take an appeal to the Court of Appeals to review that

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2 determination. No appeal was taken and the drug was found  
3 to be a new drug.

4 That is what the defendant was advised, that in  
5 fact the FDA had determined this to be a new drug, and  
6 this decision was binding on this particular defendant as  
7 a result of that Supreme Court decision.

8 THE COURT: All right. I'll await your  
9 memoranda, with pleasure, I guess.

10 When are we going to get them?

11 MR. ALTIER: On Tuesday, your Honor. You have  
12 it scheduled for trial. I notified my client to be  
13 available on Tuesday. I can have him here at 10. But  
14 I wondered, since I'm actually trying the case on Monday  
15 and I know you are going to be preparing the stipulation,  
16 if we could put it on for some time during the day Tuesday,  
17 fitting it into your calendar. so that we could in the  
18 meantime in the morning work out the stipulation.

19 THE COURT: I would also like guidance in  
20 establishing the factual basis for a plea from the  
21 defendant. The questions I need to put to him are not  
22 exactly a routine thing that one carries around in the  
23 back of his head.

24 What day would you like to do it? I will  
25 probably be having trials going on that I juggle around



1 jgs

2 with the criminal cases. So I will undoubtedly have a  
3 trial going all day.

4 MR. ALTIER: Could Mr. Pedowitz and I speak on  
5 it today, right now, see what our schedules are --

6 MR. PEDOWITZ: My schedule can accommodate  
7 Mr. Altier's.

8 THE COURT: What is wrong with that 10 a.m.,  
9 Mr. Altier?

10 MR. ALTIER: On Tuesday? Fine. The only  
11 problem is I will not have had a chance, I don't think,  
12 to have reviewed the stipulation. This afternoon I am  
13 going to Pennsylvania to get treatment for my back, which  
14 is 4 o'clock this afternoon. So I am going to get going  
15 from here. On Monday I am actually on trial. So I won't  
16 get a chance to look at that stipulation.

17 MR. PEDOWITZ: I think the stipulation is going  
18 to be very simple to draw. In fact, I've drawn one in  
19 another case. We will simply indicate that the defendant  
20 preserves his right to appeal, that the Court agrees to  
21 this, and I don't think it would be complex at all.

22 MR. ALTIER: Then 10 o'clock will be fine.  
23 I just didn't want to be haggling out here over a stipula-  
24 tion.

25 THE COURT: I don't think the stipulation will

1 jgs

2 be difficult. I am sure Mr. Pedowitz can draw it in a  
3 way that will preserve your rights. That is everyone's  
4 intention.

5 MR. ALTIER: Why don't I agree to be here at  
6 nine with you and then we can have that time and we'll put  
7 it on at 10.

8 THE COURT: All right. 10 o'clock, as we have  
9 it scheduled now.

10 All right. It is a very interesting problem,  
11 gentlemen. I appreciate your arguments.

12 MR. PEDOWITZ: I agree, your Honor. You had  
13 asked about the date on which we could have a memo in.

14 THE COURT: Yes. How about that? I suppose  
15 you should go forward.

16 MR. ALTIER: I suppose that is true.

17 THE COURT: It is your motion.

18 MR. ALTIER: I would like until the end of  
19 next week to put in a brief, your Honor.

20 THE COURT: It is all right with me. And once  
21 he pleads, it is off my calendar. Then we can play with  
22 it all we want to.

23 MR. ALTIER: Then, if I could have two weeks I  
24 would appreciate it. I don't want to overreach, but it  
25 is a good issue.



1 jgs

2 MR. PEDOWITZ: I certainly think we can have  
3 something in within a week. Indeed, we have a prelimin-  
4 ary draft of the memo already.

5 THE COURT: That's all right with me. If you  
6 want to take two weeks, the Government will reply in a week.  
7 How is that?

8 MR. PEDOWITZ: Fine, your Honor.

9 MR. ALTIER: Very good.

10 THE COURT: So that would be February 6.  
11 I will get the defendant's brief by January 30th and the  
12 Government's reply by February 6.

13 MR. PEDOWITZ: Fine.

14 THE COURT: All right.

15 ---  
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25

## 1969 STIPULATION AND ORDER.

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Attorneys for Plaintiff

FILED

FEB 13 1969

CLERK, U. S. DISTRICT COURT  
 CENTRAL DISTRICT OF CALIFORNIA  
 BY *[Signature]* DEPUTY

ENTERED

UNITED STATES DISTRICT COURT

FEB 13 1969

CENTRAL DISTRICT OF CALIFORNIA

CLERK, U. S. DISTRICT COURT  
 CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,  
 Plaintiff,

v.

Civil No. 67-1091 F

47 individually cartoned VIALS,  
 more or less, labeled in part:

(vial and carton)  
 "VIRO-ZYME

etc.,",

Defendant.

MARCEN LABORATORIES, INC.,

Claimant.

STIPULATION AND ORDER

WITHDRAWING CLAIM

AND ANSWER

It is hereby stipulated by the parties to this proceeding, through their respective counsel and subject to the approval of the Court, as follows:

BEST COPY AVAILABLE



## 1969 STIPULATION AND ORDER

1. Claimant may and hereby does withdraw its Claim and Answer without prejudice to any litigation other than the instant case and without admitting any of the allegations in the Amended Complaint.

2. Claimant will pay court costs and fees in the sum of \$35.00, payable to the Treasurer of the United States and Marshal's costs, fees, and other proper expenses in the sum of \$22.42, payable to the United States Marshal.

Claimant represents to the Court that it has discontinued the marketing of 9 of the 16 drugs under seizure in this proceeding, and that, with respect to the remaining 7 drugs, claimant is drastically revising its promotional material which it will present to the Food and Drug Administration for comment.

WM. MATTHEW BYRNE, JR.  
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FREDERICK M. BROSIO, JR.  
Assistant U. S. Attorney  
Chief, Civil Division

*Larry L. Dier*  
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Attorneys for Plaintiff,  
United States of America

*Ossimile - Plus Caps*  
*Ossimile - Plus Caps*  
*Ossimile, Caps*  
*Vibro-2400 Caps*  
*Lipo-K Caps*  
*Lipo-K Caps*  
*Nimotensin Caps*

80a

1969 STIPULATION AND ORDER

*Marshall Gumbiner*  
MARSHALL GUMBINER

Attorney for Claimant,  
Marcen Laboratories, Inc.

IT IS SO ORDERED:

This 13<sup>th</sup> day of February, 1969.

*Walter D. [illegible]*  
UNITED STATES DISTRICT JUDGE



Services of ~~three~~ <sup>two</sup> copies of  
the within *Appendix* is  
hereby admitted this \_\_\_\_\_ day  
of \_\_\_\_\_

